



**OVERSIGHT CONTROLS IN THE STATE'S MEDICAID
PRESCRIPTION DRUG PROGRAM**

**From The Office Of State Auditor
Claire McCaskill**

The Department of Social Services needs to implement more effective controls to prevent abuse and unnecessary expenditures in the Medicaid prescription drug program.

**Report No. 2002-29
April 18, 2002
www.auditor.state.mo.us**

PERFORMANCE AUDIT



Office of
Missouri State Auditor
Claire McCaskill

April 2002

State Medicaid program cannot quickly identify or prevent potential abuse by prescription drug recipients

Missouri paid \$272 million (40 percent of the \$681 million total drug cost) to fill prescriptions for 420,000 Medicaid recipients in fiscal year 2001. While many recipients received these prescriptions for legitimate medical needs, the state program cannot assure the necessity of all these expenditures. Auditors found signs of controlled substance abuse in the state program and ineffective controls to timely identify or prevent such activity.

Recipients visit multiple doctors, pharmacies for prescriptions

More than 3,900 Medicaid recipients over two fiscal years (2000 and 2001) visited 5 or more prescribers and obtained \$8.7 million in tranquilizers, painkillers and opioids. In some cases, several doctors in the same medical group treat recipients, which can justify some multiple prescribers. But auditors also found at least 10 recipients who, in one year, visited 19 to 53 doctors, and up to 25 different pharmacies, for prescriptions. Prescription drug industry experts have said recipients addicted to such drugs see several doctors (known as “doctor shopping”) and use numerous pharmacies to support and disguise their habit. (See page 4)

More than a year passes before program stops potential abusers

Program officials, since January 2000, have identified 400 recipients potentially abusing prescription drugs. But officials often took up to a year before restricting recipients to one prescriber and one pharmacist to curb diversion. In one case, a potential abuser identified in April 2000 was still unrestricted 21 months later. This recipient visited four prescribers and obtained 40 controlled substance prescriptions since identified. (See page 7)

Pharmacies are not forced to deny an overlapping narcotics script

The program automatically notifies pharmacies when a recipient requests another controlled substance in the same therapeutic class or within overlapping time periods. But the program does not deny claim payment and the pharmacy can override the alert. Many patients have a valid need for drugs in the same therapeutic class, such as a terminally ill patient who takes both pain relief and anti-anxiety drugs. But auditors also found patients with potentially invalid usage patterns. One recipient went to 10 prescribers and obtained 26 prescriptions in 90 days of oxycodone-based drugs, considered of high potential abuse by the Drug Enforcement Administration (DEA). Although pharmacists received 17

YELLOW SHEET

automatic alerts on this recipient indicating overlapping prescriptions or therapeutic duplication, the prescription were filled, and the claims paid. (See page 5)

State program responds with restrictions to some increasingly abused prescriptions

Program officials realize recipients' potential misuse of Oxycontin®, a drug increasingly abused and at the center of current Attorney General Medicaid fraud investigations. Several other states have limited the amount of Oxycontin® obtained by Medicaid recipients.

Oxycontin® is legitimately prescribed to patients suffering intractable pain, but the DEA has also seen illicit sales of the drug rise, with prices up to \$80 a tablet. Auditors noted the number of Oxycontin® prescriptions in Missouri increased 64 percent between fiscal years 2000 and 2001. In addition, state Medicaid fraud investigators are looking into five recipients obtaining Oxycontin® for potential sale. (See page 15)

Oxycontin®'s manufacturer has worked with states to institute a "hard edit" on the drug, which blocks payment when Oxycontin® prescriptions exceed certain guidelines. State officials said systems should be in place by mid-April to allow similar maximum daily quantity edits. (See page 18)

Reports are available on our web site: www.auditor.state.mo.us

**OVERSIGHT CONTROLS IN THE STATE'S MEDICAID
PRESCRIPTION DRUG PROGRAM**

TABLE OF CONTENTS

	<u>Page</u>
STATE AUDITOR'S REPORT	1
RESULTS AND RECOMMENDATIONS.....	3
1. Better Controls Could Prevent Abuse and Unnecessary Medicaid Program Expenditures	3
Conclusion	9
Recommendations.....	9
2. Restricting the Amount of Selected Narcotics Recipients Can Obtain Should Help Prevent Drug Diversion in the Medicaid Program	15
Conclusion	18
Recommendations.....	18
 APPENDIXES	
I. OBJECTIVES, SCOPE AND METHODOLOGY.....	20
II. BACKGROUND	22



CLAIRE C. McCASKILL
Missouri State Auditor

Honorable Bob Holden, Governor
and
Kathy Martin, Director
Department of Social Services
and
Gregory A. Vadner, Director
Division of Medical Services

The State Auditor's Office audited the Division of Medical Services' (the division) Medicaid prescription drug program. The objectives of the audit were to determine (1) the extent Medicaid recipients visited multiple prescribers to obtain prescriptions for controlled substances, and (2) policies and procedures for detecting and preventing abuse in the program.

Audit tests show thousands of recipients have visited multiple doctors to obtain various quantities of narcotics and other controlled substances. While many of the recipients may have obtained these prescriptions for legitimate medical needs, the state does not have sufficient controls in place to ensure unnecessary or abusive drug usage is timely identified. The quantities of drugs obtained by many individuals indicate potential waste and abuse in the drug program. This abuse could have been prevented if the division had implemented readily available automated controls used by other states.

Audit tests also disclosed, during fiscal year 2001, recipients obtained 64 percent more OxyContin® than during fiscal year 2000. The federal Drug Enforcement Administration has reported this drug can be sold on the streets for up to \$80 a tablet. The state Attorney General's Office is investigating several Medicaid recipients who obtained OxyContin® for potentially illicit street sales.

The audit was conducted in accordance with applicable standards contained in *Government Auditing Standards*, issued by the Comptroller General of the United States, and included tests of the procedures and records as were considered appropriate under the circumstances.

A handwritten signature in black ink, reading "Claire McCaskill". The signature is fluid and cursive, with the first name "Claire" and last name "McCaskill" clearly distinguishable.

Claire McCaskill
State Auditor

January 22, 2002 (fieldwork completion date)

The following auditors contributed to this report:

Director of Audits:	William D. Miller, CIA
Audit Manager:	John B. Mollet
In-Charge Auditor:	Lori Bryant
Audit Staff:	Julie Vollmer
	Tania Williams

RESULTS AND RECOMMENDATIONS

1. Better Controls Could Prevent Abuse and Unnecessary Medicaid Program Expenditures

Over 3,900 Medicaid recipients visited 5 or more physicians and other authorized prescribers and obtained numerous overlapping prescriptions for various quantities of narcotics and other controlled substances during the 2 years ended June 30, 2001. While many of the 3,900 recipients may have obtained these prescriptions for legitimate medical needs, the state does not have sufficient controls in place to ensure unnecessary or abusive drug usage is timely identified. Taxpayers spent more than \$8.7 million for the drugs received by these recipients. In addition, it cost the Medicaid program up to \$31 for an office visit each time a recipient visited a different prescriber to obtain a prescription. State regulations (13 CSR 70-4.070) define misutilization of Medicaid medical services as the act of seeking or obtaining medical services, or both, from a number of like providers and in quantities that exceed current medically necessary levels. Division of Medical Services' (division) procedures restrict treatment of recipients to a single prescriber and pharmacy when misutilization is identified which occurred for 400 recipients during the period January 2000 to August 2001.¹ Controls being used do not proactively identify and deter abusive practices.

Federal requirements for controls in the Medicaid program

Federal regulations require state Medicaid programs to provide certain basic medical services such as inpatient hospital and physician care; and optional services such as dental, prescription drugs and personal care. Over 420,000 residents obtained medications at minimal or no cost through the Medicaid program during state fiscal year 2001. These drugs cost \$681.4 million of which approximately 60 percent was paid for from federal funding.

To promote patient safety, control costs and prevent fraud and abuse in the Medicaid prescription drug program, federal law requires states to perform drug utilization reviews. The reviews include prospective screening for potential inappropriate drug therapies such as over-utilization, drug-drug interaction, or therapeutic duplication. The division defines therapeutic duplication as the prescribing and dispensing of the same drug or two or more drugs from the same therapeutic class when overlapping time periods of drug administration are involved and when the prescribing or dispensing is not medically indicated. A hypothetical example of therapeutic duplication would be (1) on Monday a Medicaid recipient visits one physician and obtains a prescription for a 10-day supply of a pain reliever, and (2) on Tuesday the Medicaid recipient visits a different physician and obtains a 10-day prescription for the same drug. Experts report that drugs from the two major therapeutic classes of controlled substances (antianxiety drugs and analgesics/narcotics) have addictive qualities that increase their potential to be inappropriately used by recipients.

¹ Division of Medical Services officials could only provide recipient restriction data for part of the audit period.

Abuse of prescription drugs has become a national concern

The vice president of the National Community Pharmacists Association estimates misuse and abuse of medications has more than a \$100 billion impact on the nations' health care costs. This comment came at a National Institute on Drug Abuse meeting and news conference in April 2001. At the news conference, the institute and seven other organizations representing the elderly, pharmacies, drug manufacturers, and patients announced they are starting a campaign to combat, "a dangerous new drug trend," the non-medical use of prescriptions. Experts from the prescription drug industry commented that many patients taking sedatives, stimulants, tranquilizers, painkillers, or opioids (narcotics), begin to use the pills inappropriately and can slip into an addiction cycle that dominates their lives and damages their health. Eventually they need more and more of the drug to achieve the same effect. The experts further commented that patients habituated to the drugs may "doctor shop" to find physicians who will prescribe the pills, and some addicts will establish accounts at different pharmacies to disguise the number of pills they are actually using.

Non-medical use
of prescriptions
costs \$100 billion

Potential abusive behavior is occurring in the Medicaid prescription drug program

Over 3,900 Medicaid recipients visited multiple prescribers to obtain various quantities of tranquilizers, painkillers, and opioids during the 2 years ended June 30, 2001, at a cost of \$8.7 million. Division guidelines define potential misutilization of pharmacy services to include:

- Recipient uses multiple prescribers and one or more pharmacies to obtain controlled substances.
- Recipient alternates use of prescribers and pharmacies to obtain controlled substances.

Table 1.1 ranks controlled substance recipients by the number of prescribers visited and includes prescriber and prescription data. The number of prescribers came from division databases and was controlled for duplicates. However, our controls could not account for doctors within the same medical group who share recipients' records. Division staff did not track the prescriber group data during our audit period. The lowest number of prescribers seen by the recipients in the table is 19.

Table 1.1: Top Ten Recipients Based on the Number of Prescribers Visited

Recipient	Fiscal Year 2000				Fiscal Year 2001			
	Prescribers Visited	Pharmacies Used	Drug Costs	Prescriptions Filled	Prescribers Visited	Pharmacies Used	Drug Costs	Prescriptions Filled
1	53	25	\$ 661	92	33	12	\$ 1,068	80
2	42	12	804	76	26	12	1,206	84
3	38	5	2,510	92	24	9	4,836	65
4	29	12	1,665	56	23	18	1,313	45
5	27	3	5,233	92	22	14	1,166	64
6	27	9	667	62	22	8	2,262	62
7	27	18	1,365	79	22	3	1,158	43
8	26	9	317	52	20	5	482	38
9	24	1	1,542	59	19	3	10,383	83
10	24	9	1,990	133	19	11	1,100	90

Source: Medicaid paid claims data

The large number of prescribers and pharmacies visited and prescriptions obtained indicate potential abusive behavior by Medicaid recipients. Audit tests showed the average number of prescriptions for the 3,900 recipients was 33. During fiscal year 2000, one recipient visited 53 different prescribers and obtained 92 prescriptions for controlled substances. In addition to paying for this recipient's prescription drugs, the Medicaid program also pays the costs for physician office visits, which range from \$7 to \$31, depending upon the services provided. Accordingly, when this recipient visited 53 different prescribers to obtain controlled substances, the office visits cost the program between \$397 and \$1,669.

Majority of recipients obtained drugs with high potential for abuse

Over 3,000 of the 3,900 recipients obtained drugs in the analgesics/narcotics class, which are typically prescribed to alleviate moderate to severe pain. The Drug Enforcement Administration (DEA) has placed many of the drugs in this therapeutic class in Schedule II of the Controlled Substance Act, because (1) the drugs have a high potential for abuse, and (2) abuse of these drugs may lead to severe psychological or physical dependence.² Analysis showed over 2,670 (68 percent) recipients obtained Schedule II narcotics (hydrocodone and/or oxycodone) for which the DEA has reported substantial increases in abuse and illicit street sales. According to the DEA, hydrocodone and oxycodone pills/tablets are illicitly sold for \$2 to \$80 apiece.

The division's Medicaid claims processing system automatically notifies pharmacies when a recipient is obtaining overlapping prescriptions for drugs in the same therapeutic class, but it does not automatically deny the claim. The pharmacy can elect to either fill or not fill the prescription. Over 2,700 of the 3,900 recipients who obtained controlled substances, each received at

Overlapping
prescriptions
obtained

² See Appendix II for information related to the Controlled Substance Act.

least 5 therapeutic duplication alert messages on prescriptions submitted for processing. Many of these prescriptions may have been denied if there was a system to require the pharmacies to contact the division's help desk before filling the prescription. Table 1.2 shows an example of one recipient who received 26 prescriptions in a 90-day period.

Table 1.2: Recipient Who Visited Multiple Prescribers and Obtained Overlapping Prescriptions for Schedule II Drugs in the Same Therapeutic Class

Date of Service	Drug Name	Number of Pills/Tablets	Prescriber Number	Alert ¹ Code 1	Alert ¹ Code 2	Amount Paid
07/02/00	OXYCONTIN®	84	1			\$312.26
07/06/00	ROXICET®	30	2	692		6.57
07/12/00	OXYCONTIN®	50	2			187.52
07/20/00	OXYCONTIN®	50	2			187.52
07/20/00	ROXICET®	30	2	692		6.57
07/25/00	ROXICET®	30	3	692		6.57
07/26/00	OXYCONTIN®	50	3	692		187.52
08/03/00	OXYCONTIN®	14	4	692		100.68
08/03/00	ROXICET®	50	4			8.22
08/09/00	OXYCONTIN®	50	2			187.52
08/09/00	ROXICET®	30	2	692		6.57
08/16/00	OXYCONTIN®	12	5			28.90
08/23/00	OXYCONTIN®	28	6	692		106.81
08/23/00	OXYCONTIN®	14	6	692	691	33.04
08/23/00	ROXICET®	60	6			9.04
09/04/00	OXYCONTIN®	14	7	692		100.68
09/04/00	OXYCONTIN®	14	7	692	691	55.45
09/04/00	ROXICET®	30	7			6.57
09/11/00	OXYCONTIN®	8	8			59.28
09/12/00	OXYCONTIN®	50	2	691		187.52
09/12/00	ROXICET®	30	2	692		6.57
09/19/00	OXYCONTIN®	60	9			224.21
09/19/00	ROXICET®	30	9	692		6.57
09/29/00	OXYCODONE HCL	140	2	691		37.29
09/29/00	OXYCONTIN®	100	2			693.99
09/30/00	ROXICET®	40	10	692		7.39
Totals		<u>1,098</u>				\$ <u>2,760.83</u>

¹ Alert code 691 indicates "Duplicate Therapy Same Drug." Alert code 692 indicates "Therapeutic Duplication."

Source: Medicaid paid claims data

As the above table shows, the recipient alternated visits to 10 different prescribers during a 90-day period and obtained numerous overlapping prescriptions of narcotics, which were all oxycodone based Schedule II drugs. For example, on September 29, 2000, the recipient obtained 26 prescriptions which resulted in 13 therapeutic duplication alerts and 4 duplicate therapy same drug alerts, which indicated the recipient was obtaining overlapping prescriptions for drugs in the same therapeutic drug class.

Process to prevent prescription drug abuse is not effective

Division data shows that it can take more than a year from the time a recipient begins visiting multiple prescribers and obtaining controlled substances until the time he/she is restricted to a single prescriber and pharmacy. For example, one recipient was assigned in April 2000 to be restricted to a single prescriber and pharmacy, but as of December 2001 (21 months later) the division had been unable to get a physician to take the recipient. During the 21-month period the recipient visited 4 prescribers and obtained 40 prescriptions for antianxiety drugs and narcotics. Medicaid recipients can visit numerous providers and obtain large quantities of drugs before the division identifies them. Division staff identify and restrict potential drug abusers by (1) reviewing claims paid during a previous 3-month period, and (2) finding a single prescriber and pharmacy, that agrees to take the recipient (which may take some time if a physician and/or pharmacy will not take the recipient).

Recipients can easily abuse the program

Since January 2000, division staff have identified over 400 Medicaid recipients who visited multiple prescribers to obtain excessive amounts of controlled substances. Although these recipients were restricted to seeing only one prescriber and/or pharmacy it was not until up to a year after they had visited several prescribers and obtained large quantities of controlled substances at substantial costs to the Medicaid program. Due to lack of resources, division officials did not review thousands of other recipients who visited multiple providers and potentially obtained excessive amounts of controlled substances.

Our analysis shows the division restricted 140 of the 3,900 recipients we identified to a single prescriber and pharmacy, but not until after they had visited 5 or more prescribers and obtained the questioned quantity of drugs. Audit staff submitted 22 of the 3,900 recipients, who had not been restricted to one prescriber and/or pharmacy, to division officials for review of drug acquisition propriety. Division officials acknowledged problems with utilization for 9 of the recipients by assigning 4 for restriction to a single prescriber and sending 5 for further investigation; and indicated all 22 recipients needed to be reviewed regardless of the outcome. Several states use automated systems to prevent Medicaid recipients from obtaining excessive drugs at the time of sale thereby saving program expenditures and eliminating the need for extensive after-the-fact reviews.

During our audit, division officials confirmed our concerns about possible abusive behavior by developing two frequency distributions of Medicaid recipients for the period October 11, 2001, to January 11, 2002. The first distribution profiled the number of recipients and the number of prescribers visited. The second distribution profiled the number of recipients and the number of pharmacies visited. These two distributions were not linked, thus each result was independent of the other.

Regarding the recipient to prescriber distribution, 40,053 of 474,975 recipients visited 5 or more prescribers. Over 4,200 of these recipients visited 9 or more prescribers. Regarding the recipient to pharmacy distribution, 1,602 of 476,270 recipients visited 5 or more pharmacies. These distributions represent the circumstances that should cause a review of a recipient's claims activity

Abuse can be prevented before it occurs

based on division guidance for potential misutilization discussed on page 4. Although the guidance does not include recipient to pharmacy activity, the division pharmacy director indicated visits to more than four pharmacies would be cause for concern.

More effective controls are available to prevent drug abuse in the Medicaid program

A more efficient and cost-effective control, which the division has not implemented, would automatically deny at the time of submission overlapping prescriptions for drugs in the same therapeutic drug class. The division pharmacy director stated implementing this control is difficult because many Medicaid recipients have a valid need to obtain different drugs from the same therapeutic class. Nevertheless, several states, including Kentucky and Illinois, have implemented edits to automatically deny payment for prescriptions that involve therapeutic duplication, but still allow recipients who need drugs from the same therapeutic class to obtain them. For example, when a prescription is automatically denied due to therapeutic duplication, (1) the pharmacy must contact the prescriber to determine if it is medically necessary for the recipient to obtain the prescription, and if it is, (2) the pharmacy or prescriber can contact the Medicaid help desk to obtain an override to fill the prescription. Conversely, if the prescriber states it is not medically necessary to obtain the prescription, the prescription is not filled. The division's practice of paying bills and then pursuing abuses after the fact ("pay and chase") to prevent abuse in the prescription drug program simply does not work.

The division plans to add automatic denial edits to the Medicaid claims processing system

The division is soliciting proposals from contractors to implement an enhanced pharmacy management program. This program would add selected edits to the division's Medicaid claims processing system. These edits would generate messages to pharmacies to deny prescription claims prompting the pharmacy to contact the help desk for an override. Division staff stated a decision has not been made to automatically deny prescription claims that meet the criteria for therapeutic duplication.

The division is also initiating a disease management intervention system which would weight multiple factors to better understand a recipient's claims activity and identify potential abusers. The following factors would be included in the profile:

- Number of prescribers visited.
- Number of pharmacies visited.
- Drug(s) identifications.
- Drug(s) doses.
- Medical diagnosis.

Conclusion

Abuse of controlled substances exists in the Medicaid prescription drug program and oversight controls do not timely identify and stop these activities. The division has restricted several hundred Medicaid recipients to visiting only one prescriber, but not until after they successfully visited several prescribers and obtained inappropriate amounts of drugs. Until the division implements automated controls to prevent prescription drug abuse, these practices will continue. While the division is developing systems to better profile recipients, without a control to alert division officials to review potential misutilization cases in a real-time mode, potentially abusive practices of some individuals will not be detected early enough. Automated edit routines to identify these recipients before drugs are dispensed would give some assurance that potential abusers can be stopped.

Recommendations

We recommend the Director, Department of Social Services:

- 1.1 Implement edits that will automatically deny, at the time of sale, prescriptions that result in therapeutic duplication alerts; especially for drugs from the two major therapeutic classes of controlled substances (antianxiety drugs and analgesics/narcotics).
- 1.2 Establish criteria for authorizing edit overrides for recipients with medical needs to obtain multiple drugs from the same therapeutic class.

Department of Social Services Responses

DMS is in the process of implementing medical databases to prospectively review all claims for appropriateness of therapy. Claims outside the accepted medical practice models will be rejected and juried through the drug prior authorization process. Absolute, automatic denial, without being medically reasonable, is inconsistent with good medical practice and fails to allow for concurrent therapy with synergistic therapeutic classes.

DMS will continue to allow recipients' medical practitioners to be in charge of their therapy and make valid medical decisions regarding patient care. DMS will continue to provide various edits to alert practitioners to potential therapy problems.

DMS will establish therapeutic criteria and algorithms that appropriately allow for the use of necessary pain medication in the same or compatible therapeutic classes. Additionally, the new Program Integrity Unit, enhanced Prospective DUR Programs, Disease State Management Programs, and enhanced retrospective DUR are vehicles that will assist in managing these challenges.

The following comments were made to sections of this issue.

Better Controls Could Prevent Abuse and Unnecessary Medicaid Program Expenditures

Missouri Medicaid has a history of reviewing suspicious or questionable claims and making appropriate referrals for further investigation. DMS works closely with the Attorney General's office in these cases. Our recent system changes, our new Program Integrity Unit, and our forthcoming Disease State Management Program will significantly strengthen these activities.

The SAO findings are grossly overstated when compared to the finding of DMS pharmacists. When recipients were reviewed as unduplicated patients and weighted according to a risk analysis model a different analysis conclusion was reached.

The simple fact that a patient saw multiple physicians, obtained multiple prescriptions, or had multiple office visits is not in itself indicative of abuse. Multiple physicians identified in our research were duplications or visits to multiple physicians in the same practice or clinic. No corrections were made by auditor staff to fully account for this fact.

DMS is essentially an insurance agency for the indigent. DMS continuously manages the potential risk of abuse, while not arbitrarily denying patient care, or limiting patients' access to medical practitioners for treatment. One of the safe guards to the use of Schedule II controlled substances is the federal requirement that a new prescription be obtained prior to each filling. To follow the logic of the SAO, one would need to conclude that thousands of recipients were in collusion with tens of thousands of physicians for the sole purpose of obtaining controlled substances.

DMS review of claims from July 1 through December 31, 2001 yielded only 107 Medicaid recipients that warranted additional examinations due to their high Oxycontin® use. The review was based on observed utilization (dosage, medication strengths, quantity, frequency of fills), diagnoses, number of prescribers, and number of pharmacies.

Of those reviewed, six went to Surveillance Utilization Review Services (SURS) of the Program DMS Integrity Unit for additional review, four were locked in, 19 were identified for additional medical review and 66 were identified as potentially benefiting from disease state or case management programs. The remainder required no immediate action and will again be reviewed in future Drug Utilization Review (DUR) activities.

The audit fails to point out that many of the sickest DMS recipients are dually eligible for Medicare. By federal law, DMS is unable to "lock in" any dually eligible patient. The "lock in" process is governed by federal guidelines and Missouri regulation 13 CSR 70-4.070. This rule basically defines the process for allowing patients to receive services from only one of each provider, i.e. one prescriber and one pharmacy. The rule also provides the patient a fair hearing opportunity.

SURS unit is part of the DMS Program Integrity Unit and is composed of three nurses, one physician, one Certified Public Accountant, one medical records technician and support staff.

The Drug Utilization Review Board is an advisory board to DMS, established by statute and appointed by the Governor. The DUR Board is composed of six actively practicing physicians, six actively practicing pharmacists, and one certified quality assurance registered nurse. They are required to meet quarterly and charged with monitoring the drug usage and prescribing practices in the Medicaid program. Additionally, the board is supplemented by six regional advisory committees comprised of physician and pharmacists appointed by the board to assist in the review process.

Federal requirements for controls in the Medicaid program

It is common practice for physicians to use a sustained release oxycodone for chronic pain relief and to supplement the controlled release product with a rapid release product when pain “breakthrough” occurs. It is also common therapeutic practice to add anti-anxiety drugs to a pain control regimen. Patients in pain, especially with terminal illness, have accompanying anxiety with their illness. The combination use of anti-anxiety drugs is beneficial in pain relief because of the synergistic effect they have with the analgesic medications. Therefore, a duplicate from the same therapeutic class is not necessarily an issue, nor is the addition of anxiolytic agent. Both draw edits to highlight the potential problem to the practitioner.

The Disease State Management Program, which is in process of implementation, will add another level of review and monitoring for patients identified through edits, population based interventions, and our drug utilization review (DUR) process. The DUR process has recently been augmented with a risk assessment review model, which will more effectively identify patients at greatest risk for iatrogenic disease.

The enhanced prior authorization process administered through medical databases will be available within the next few months. This system will add an additional tool to prospectively review a patient's medications prior to adjudicating the incoming claim. Claims outside the medical database will be rejected. A new help desk was implemented in March of 2002. This will provide health care providers access to information and assistance in obtaining coverage for needed medications that have been rejected for closer scrutiny.

Abuse of prescription drugs has become a national concern

Certainly, these facts are not new information nor are they unique to the Missouri Medicaid program; they affect all payors. The \$100 billion impact was not directed to problems with controlled substance alone. The quote was part of the findings by Dr. Lyle Bootman in an article in the Annals of Internal Medicine; referring to the lack of consistent care used in the prescribing and monitoring of ALL prescription medications. The findings were not clinically based but were fiscally based on a cost of illness model.

A cost of illness model reflects all direct and indirect costs associated with a specific disease process. In this case, not only were the costs of drugs included but additionally the direct costs of other resources used to treat the drug misadventures. Often indirect cost related to lost wages, travel, and inability to provide family related functions are also included.

Potential abusive behavior is occurring in the Medicaid prescription drug program

The points enumerate only two of several potential concerns. In reviewing such patients there may be many valid reasons for the ordered therapy. This illustrates exactly the reason DMS has devoted the additional resources to review and monitor such activity. This is the reason DMS worked with the General Assembly to fund new initiatives that are designed to provide increased scrutiny. The following vehicles will manage these challenges:

The new Program Integrity Unit

- additional staff dedicated to provider surveillance*
- new electronic systems to detect aberrant activity*

Prospective Drug Use Review Programs

- clinical edits using evidence based medical models to screen ALL incoming prescriptions*
- minimum and maximum edits on medication utilization*
- fiscal integrity edits on all incoming claims*

Disease State Management Programs

- patients identified by a risk assessment model*
- physician pharmacist teams to review identified patients*

Enhanced retrospective DUR

- evidence based medical models to review patient medication therapy*
- integration of all medical provider claims to the review process*

Majority of recipients obtained drugs with high potential for abuse

The facts pointed out by the SAO in and of themselves are not indicative of the conclusions drawn; they are rather indications for review by trained practitioners. This is precisely the focus of the current DMS initiatives. The programs utilize licensed and specially trained pharmacists and physicians to provide the new services. These practitioners are authorized to provide additional oversight and management for the patients identified as "most at risk". The Disease State Management Programs will utilize these professionals to carefully review, monitor, and manage the care of the identified patients.

Process to prevent prescription drug abuse is not effective

The SAO is identifying a potential program limitation already noted by DMS. The solution is in progress. In the past few months DMS has enhanced its Program Integrity Unit. The first of April additional bids were let to enhance and expand the technology used to detect program fraud and abuse. The Pharmacy Enhancement Program has been underway since October 2001. Many changes are in progress. The enhancement to the Prospective DUR Program, the new Disease State Management Program, and the enhanced retrospective DUR have already been described. The initiatives clearly add timely and effective new tools to deal with the identified shortfalls in a logical, effective, step wise fashion. The process will provide the needed surveillance while allowing access to needed care by Missouri's most vulnerable citizens.

DMS, through our prospective and retrospective drug use review, has always routinely examined all Medicaid prescriptions for appropriate medical use, and potential abuse and diversion. Our review determined the vast majority of the cases identified by the SAO to be medically reasonable, when factoring in the patient's medical diagnosis and history, and the normal progression of severely ill patients from a general practice doctor to a specialist or series of specialists. The result was a small number of potential abuses that were dealt with through additional surveillance activity or referral to the Attorney General.

In response to the SAO's two-year review, DMS conducted an in-depth review of the last six months of 2001, which yielded only 107 Medicaid recipients that warranted additional examinations due to their high Oxycontin® use. The review was based on observed utilization (dosage, medication strengths, quantity, frequency of fills), diagnoses, number of prescribers, and number of pharmacies.

Of those reviewed, six went to Program DMS Integrity Unit for additional review, four were locked in, 19 were identified for additional medical review and 66 were identified as potentially benefiting from disease state or case management programs under development. The remainder required no immediate action and will again be reviewed in future DUR activities as are all DMS pharmacy claims.

The new and enhanced DMS programs will use these alerts, edits and the new risk assessment model to target the identified patients and place them into programs providing more oversight, review and management. The Disease State Management Program will provide the oversight for the patients' medical providers who are collaborating to bring increased focus on areas of potential concern. The activity will not stop there. The outcomes for these vulnerable patients will be reported, as will all of the activities of the new initiatives. The surveillance will not stop at this point either. Even after it appears these patients' problems are under control, they will continue to be part of the overall program surveillance. When patients are extremely vulnerable they are very likely to periodically need the closer scrutiny of the multifaceted programs DMS is employing to guard their health and prevent unnecessary expenditures for the State.

In fact, most states do not restrict the drugs referenced in this audit. Several of the states that attempted arbitrary controls have removed them after realizing they posed a barrier to adequate pain control. As noted, we do review, and refer for further scrutiny, cases with questionable utilization patterns. With our recent system changes and our Disease State Management Program, DMS will be much more able to manage these cases in a logical, consistent and medically sensitive way.

The division plans to add automatic denial edits to the Medicaid claims processing system

The proposal allows the medical database to review all claims prospectively. The only rejections would be for those failing the medical database. This involves far fewer claims than the SAO implies; the process is far more efficient and does not arbitrarily disrupt a patient's care. DMS staff would not automatically deny therapeutic duplicates because that, in and of itself, is not a reason for denial, but only an indicator to trigger closer scrutiny by the providers and/or DMS. We will be enabling this scrutiny with our Disease State Management Programs.

These are risk factors and not targeted solely to identify abusers. They are used to target patients for closer monitoring due to their greater risk for drug induced adverse effects and other iatrogenic disease issues. DMS is responsible for approximately 500,000 patients in their fee-for-service program. The program generates 15 million prescriptions per year. Over 60 percent of these services are consumed by less than 30 percent of the recipients. These patients are the most vulnerable and most at risk in the State. Management of these patients is the goal of DMS, in the hope that it will result in healthy patients being treated more efficiently and more economically.

DMS is in the process of implementing medical databases to prospectively review all claims for appropriateness of therapy. Claims outside the accepted medical practice models will be rejected and denied through the drug prior authorization process. Absolute, automatic denial, without being medically reasonable, is inconsistent with good medical practice and fails to allow for concurrent therapy with synergistic therapeutic classes.

DMS will continue to allow recipients' medical practitioners to be in charge of their therapy and make valid medical decisions regarding patient care. DMS will continue to provide various edits to alert practitioners to potential therapy problems.

DMS will establish therapeutic criteria and algorithms that appropriately allow for the use of necessary pain medication in the same or compatible therapeutic classes. Additionally, the new Program Integrity Unit, enhanced Prospective DUR Programs, Disease State Management Programs, and enhanced retrospective DUR are vehicles that will assist in managing these challenges.

State Auditor's Comments

The department director disagrees with the audit recommendations. The actions proposed by department officials do not satisfactorily identify abusers early enough in the process to have an affect on the abuse.

One of the responses needs clarification. The response stated SAO findings did not account for duplicated patients in the department databases. Upon follow up with department officials we determined they were referring to some adjusting transactions for patients which are first recorded on paper. Department staff routinely enter these adjustments in the electronic database. Therefore, the auditors had complete data to analyze. Our analysis accounted for these adjustments.

2. Restricting the Amount of Selected Narcotics Recipients Can Obtain Should Help Prevent Drug Diversion in the Medicaid Program

Division records indicate Medicaid recipients have substantially increased their use of OxyContin®, a drug which the DEA has reported to be increasingly abused because of its high potency and opiate-like effects. The state Attorney General's Medicaid Fraud Control Unit is investigating some of these recipients for potential OxyContin® diversion. Although division officials stated they are aware of potential OxyContin® abuse in the Medicaid program, they have not taken sufficient actions to restrict the amount of this drug that recipients can obtain on a monthly basis. Division officials stated it would be difficult to develop appropriate parameters and criteria to restrict the use of this drug. Nevertheless, several states have taken steps to limit the amount of OxyContin® recipients can obtain.

OxyContin® is legitimately used for pain management, but also is attractive to abusers

OxyContin® is a time-released tablet of the narcotic oxycodone a Schedule II controlled substance. OxyContin® is frequently prescribed to provide relief to patients who suffer intractable pain and is considered the drug of choice for pain management. The DEA reports the abuse of OxyContin® has increased substantially over the last year and has become a national problem. Analysis shows the amount the Medicaid program paid for OxyContin® almost doubled from fiscal year 2000 to 2001, with a 64 percent increase in the number of OxyContin® paid prescription claims. While the increase in the prescriptions for this drug may partly explain the overall cost increase, not all of the increase can be attributed to legitimate use. According to the DEA, OxyContin® can be readily sold on the street for up to \$80 per tablet.

DEA reports increased abuse of OxyContin® has occurred in several states

The DEA reports, oxycodone abuse has been a continuing problem in the United States since the early 1960's, and the abuse of a new sustained-release formulation of oxycodone, known as OxyContin®, has escalated over the last year. Drug abuse treatment centers, law enforcement personnel, and health care professionals have reported a dramatic increase in the abuse of these sustained release products in Maine, Virginia, West Virginia, Ohio, Kentucky and Maryland. Recently, abuse has spread to other states such as Pennsylvania and Florida. The estimated number of nationwide emergency room visits involving oxycodone was stable from 1990 through 1996. However, the number of visits has more than tripled with 3,190 episodes in 1996 to 10,825 in 2000. Prior to the introduction of OxyContin®, most oxycodone-containing products had a maximum of 5 milligrams per tablet or capsule. OxyContin®, however, is marketed in 10, 20, 40, and 80 milligram 12-hour time released tablets, and is altered by drug abusers for immediate release of the drug's full potency.³

³ OxyContin® was available in a 160 milligram time-released tablet, but the manufacturer suspended distribution of the 160 milligram tablets in May 2001.

OxyContin® use has substantially increased in the state's Medicaid program

The DEA reported that Missouri was one of 17 states with above average national consumption of OxyContin® during the period January 2000 through September 2000. Division records show the cost of OxyContin® products obtained by Medicaid recipients increased from \$4,928,976 in fiscal year 2000 to \$9,344,838 in fiscal year 2001 (90 percent). Analysis shows a substantial increase in the number of OxyContin® prescriptions and number of Medicaid recipients who obtained OxyContin®. Table 2.1 shows the number of Medicaid OxyContin® prescriptions, number of Medicaid recipients who obtained OxyContin®, and percent increase from fiscal year 2000 to 2001.

Table 2.1: Trend in OxyContin® Use

Fiscal Year	OxyContin® Prescriptions	Recipients Obtaining OxyContin®
2000	27,842	5,405
2001	45,636	7,860
Increase	64%	45%

Source: SAO analysis of paid Medicaid claims

Audit results showed that over 1,600 of the 3,900 Medicaid recipients who visited 5 or more prescribers to obtain large quantities of controlled substances obtained one or more OxyContin® prescriptions. From fiscal year 2000 to fiscal year 2001, the percentage of these recipients receiving OxyContin® increased by 33 percent.

Table 2.2: Medicaid Recipients' OxyContin® Activity

Number of Recipients Who	Fiscal Year	
	2000	2001
Visited multiple prescribers and obtained controlled substances	1,826	2,074
Obtained one or more OxyContin® prescription	661	986
Percentage obtaining OxyContin®	36%	48%

Source: SAO analysis of paid Medicaid claims

Medicaid recipients are involved in potential cases of drug diversion

According to the DEA, a 40 milligram OxyContin® tablet may sell on the street for \$25-\$40, and an 80 milligram OxyContin® tablet may sell for \$65-\$80, which has resulted in individuals forging prescriptions and visiting multiple doctors to obtain the drug. The Attorney General's Medicaid Fraud Control Unit is currently investigating five Medicaid recipients that

Five recipients
under
investigation

potentially obtained OxyContin® for illicit street sales, which cost taxpayers over \$400,000. The following table shows each of the five Medicaid recipients obtained large amounts of OxyContin® with street values ranging from \$600,000 to over \$1.5 million (estimated at \$1 per milligram the maximum street value).

Table 2.3: Medicaid Recipients Under Investigation

Recipient	FY 2000 Milligrams	FY 2001 Milligrams	Total Milligrams	Amount Paid By Medicaid
1	307,620	1,281,840	1,589,460	\$ 135,098
2	492,560	614,140	1,106,700	109,812
3	275,920	380,160	656,080	57,470
4	252,960	394,400	647,360	55,664
5	104,920	497,680	602,600	54,364
				<u>\$ 412,408</u>

Source: SAO analysis of paid Medicaid claims

As Table 2.3 shows, the five recipients obtained large amounts of OxyContin® in both fiscal years 2000 and 2001. Analysis also shows several other Medicaid recipients obtained unusually large quantities of 80 milligram OxyContin® tablets through single prescriptions. Ten recipients in fiscal year 2000 and 23 recipients in 2001, each obtained 300 or more 80 milligram OxyContin® tablets with only one prescription, with one recipient obtaining 850 tablets. The claims data shows these recipients obtained a 30-day supply, which indicates they were prescribed from 10 to 28 tablets per day, which is in excess of the normal dosage limit of six 80 milligram tablets per day determined by the drug's manufacturer. Seven of the recipients obtained 300 or more tablets with one 30-day prescription in both fiscal years.

The division has not taken sufficient steps to prevent abuse of OxyContin® products

Although the division's pharmacy director stated the division was aware of increased use of OxyContin® by Medicaid recipients, division staff had not performed any analyses until December 2001 to determine the extent of OxyContin® abuse by Medicaid recipients. Division officials also said they were aware of possible OxyContin® diversion by Medicaid recipients, but it would be difficult to develop appropriate parameters and criteria to restrict the use of this drug. Division officials were concerned that placing restrictions on OxyContin® would be unfair to those recipients who suffered intractable pain. A representative of the manufacturer of OxyContin® told us any daily dosage over 480 milligrams would be considered an outlier and it is at this level hard edits⁴ should be invoked before a prescription is filled. The audit results show that many recipients received far more than a daily dosage of 480 milligrams of OxyContin®.

⁴ Computer system settings that block authorization for a submitted pharmacy transaction which exceeds the defined setting limits until a Medicaid official evaluates and approves the transaction.

Several states have taken steps to prevent OxyContin® abuse in their Medicaid programs

Kentucky, Vermont and the District of Columbia require physicians to obtain prior authorization before they can prescribe OxyContin® for Medicaid recipients. In addition, seven other states have placed limits on the amounts of OxyContin® Medicaid recipients can obtain on a monthly basis, without obtaining prior authorization. For example, North Carolina limits Medicaid recipients to 6 tablets a day any strength and Maryland limits recipients to no more than 120 tablets per prescription any strength, without prior authorization being obtained.

Conclusion

The DEA has reported that OxyContin® abuse is becoming a national problem and Missouri was one of 17 states with above average national consumption in 2000. Analysis shows OxyContin® use by Medicaid recipients increased dramatically from fiscal year 2000 to 2001. Investigations by the Attorney General's Office indicate some of this increase could be for illicit street sales. The division has not taken sufficient steps to prevent OxyContin® abuse in the Medicaid program.

Recommendations

We recommend the Director, Department of Social Services:

- 2.1 Establish hard edits in the Medicaid claims processing system to block payment authorization for OxyContin® prescriptions which exceed division determined utilization guidelines.
- 2.2 Until the edit is in place, identify Medicaid recipients who are obtaining OxyContin® at or above this utilization guideline and determine if there is an appropriate medical need for the drug strength and tablet quantities prescribed.

Department of Social Services Responses

System changes will be in place by mid-April to allow maximum daily quantity edits for Oxycontin®. DMS will institute these edits and a drug authorization process to allow for the justification of medically appropriate utilization for larger dosages. DMS will continue to perform retrospective drug use review for all Medicaid recipients and for all medications.

Development of enhanced medication monitoring and medical database screening of all prescriptions will occur. Provider based disease state management for Medicaid recipients, which warrant such oversight because of their risk management index is also forthcoming. These enhancements are part of RFP B3Z02142 with bids due April 25, 2002, with implementation expected the summer of 2002. As previously discussed, these new tools are:

Enhanced Prospective Drug Use Review Programs

-clinical edits using evidence bases medical models to screen ALL incoming prescriptions

- minimum and maximum edits on medication utilization
- fiscal integrity edits on all incoming claims
- Disease State Management Programs
 - patients identified by a risk assessment model
 - physician / pharmacist teams to review identified patients
- Enhanced retrospective DUR
 - evidence based medical models to review patient medication therapy
 - integration of all medical provider claims to the review process

The following comments were made to sections of this issue.

The division has not taken sufficient steps to prevent abuse of OxyContin® products

The DMS drug use review contractor had began analysis in August 2001 at the request of the original DMS staff. DMS Pharmacy Director joined the team in October 2001. The remainder of the clinical staff, including a Clinical Pharmacist and Medicaid Specialists were in place by January 2002 intensifying the review efforts. Continued evaluations showed two pharmacies that warranted review. In addition, DMS was already reviewing three of the five patients referenced, in the above table, by the SAO. With all of the review by the SAO, the Attorney General's Office, and DMS, to date no cases have come forth with enough evidence of diversion to result in successful prosecution efforts.

The manufacturers own literature indicates a titration course and indications for 560mg twice a day or daily dosages of 14 or more tablets per day. The Drug Information Center at UMKC and local pain management physicians have indicated dosages above that level have routinely been used. There is no maximum dose of pure opioid agonists because patients do develop tolerance to such medications. This "no ceiling" effect makes individualized dosing regimens extremely important.

Tolerance and physical dependence in intractable pain patients are not signs of abuse. Tolerance is the need for increasing doses of the medication to maintain the defined effect of analgesia. DMS has and continues to search for and evaluate the Oxycontin® surveillance issues within our population.

Conclusion

OxyContin® usage in Missouri, one of 17 states identified, may be a factor of being one of the largest elderly states in the nation and the more aggressive pain management posture by the healthcare community required to administer care to the elderly. Please note the statistics cited are for ALL patients and not only Medicaid patients.

OBJECTIVES, SCOPE AND METHODOLOGY

Objectives

The objectives of the audit were to determine (1) the extent Medicaid recipients visited multiple prescribers to obtain prescriptions for controlled substances, and (2) policies and procedures for detecting and preventing abuse in the program.

Scope and Methodology

We obtained and reviewed federal and state statutes and regulations related to Title XIX of the Social Security Act (the Medicaid program) and the Controlled Substances Act. We obtained and reviewed reports from the DEA related to drug abuse and controlled substances such as oxycodone, hydrocodone, and OxyContin®. We contacted Medicaid officials from selected states, including Missouri's eight contiguous states, to determine (1) if the states used computer edits to automatically deny prescriptions that potentially involved fraud, waste, and abuse, and (2) if the states had placed restrictions on recipients' ability to obtain the drug OxyContin®.

We obtained and analyzed the division's Medicaid paid prescription drug claims for the 2 fiscal years ended June 30, 2001.

Because the division did not require pharmacies to use standard procedures to identify prescribers until fiscal year 2002, pharmacies could enter either a prescriber's name or his/her Medicaid identification number. Accordingly, some pharmacies may have entered a provider's name, while others may have entered the provider's Medicaid identification number. As a result, a computer count of the different entries in the prescriber field could overstate the actual number of prescribers recipients visited. To determine the total number of different prescribers a recipient visited, we identified the number of different prescriber names and identification numbers shown on each recipient's claims data, and recorded whichever was higher. Because division databases did not track doctors who practiced in groups, neither division personnel nor audit staff could determine the amount of duplication in the prescriber field caused by this factor. The premise is that doctors who practice in groups share medical records and therefore it is possible for a recipient to have multiple prescribers. Thus it is possible a recipient could obtain prescriptions from several prescribers without "doctor shopping." An example of a recipient's claims data from which we concluded that the recipient went to at least eight different prescribers (actual names were changed and names shown are fictitious) follows.

APPENDIX I

Prescriber	Description
241008929	number 1
SMITH	name 1
JONES	name 2
JOHNSON	name 3
JONES,CH	name 2
CARTER	name 4
COOK	name 5
HARRISON	name 6
GREEN	name 7
WARD	name 8

As the above example shows, when two last names were the same but one had initials following it, such as, JONES and JONES,CH, we assumed the prescribers were the same person. We also assumed when numbers were also shown in a recipient's claims data, it was associated with one of the names and did not count it. Accordingly, the results of our analyses may be understated.

We obtained, reviewed, and discussed with appropriate division officials policies and procedures for detecting and preventing abuse in the Medicaid prescription drug program. We obtained listings of Medicaid recipients the division identified as abusing this program and restricted to visiting only one doctor and/or pharmacy.

BACKGROUND

Medicaid Program

Authorized in 1965 under Title XIX of the Social Security Act, Medicaid is a federally-aided, state-run medical assistance program. Services provided by Missouri's Medicaid program include those required by federal regulations such as hospital, physician, and skilled nursing home care services. The state's Medicaid program also provides optional services such as dental, prescription drugs, and personal care as authorized by the General Assembly. The state's Medicaid program is jointly funded by state and federal funds. In fiscal year 2002, program appropriations were \$4.3 billion which will be approximately 60 percent paid for from federal funding. The Department of Social Services, Division of Medical Services (the division) is responsible for administering the Medicaid program.

The state's Medicaid program has provided eligible Missouri residents prescription drug services at nominal or no cost since 1967 and this service is estimated to cost \$744 million during fiscal year 2002. Because of growing concern over the increased use and cost of prescription drugs, the Social Security Act was amended in 1990 requiring states to implement Drug Utilization Review programs by January 1, 1993. The Act mandated that these reviews include prospective screening for potential drug problems due to therapeutic duplication, drug-disease contradiction, drug-drug interaction, incorrect drug dosage, incorrect duration of treatment, drug-allergy interactions, and clinical abuse or misuse.

The division uses an automated system, which includes a database of patients' drug and medical histories, to prospectively review and process Medicaid prescription claims. When a Medicaid patient submits a prescription to be filled, the pharmacist transmits recipient information to a statewide database via the automated system. In an on-line, real-time environment, after verifying the recipient's eligibility, the system screens the prescription against the recipient's known Medicaid medical and prescription history. The system then sends the pharmacy a message indicating whether the claim is "payable" (valid), or whether any potential drug therapy problem, such as therapeutic duplication exists. If a potential drug therapy problem exists, the pharmacist consults with the recipient and/or the recipient's physician, depending upon the seriousness of the problem. After such consultation and according to the pharmacist's judgment, the pharmacist may fill the prescription, resubmit the claim for a different drug prescribed by the physician, or submit a reversal to cancel the claim.

Controlled Substances Act

The Controlled Substances Act places all substances regulated under existing federal law including prescriptions into one of five schedules. This placement is based upon the substance's medical use, potential for abuse, and safety or dependence liability. The Act also provides a mechanism for substances to be controlled, or added to a schedule; decontrolled, or removed from control; and rescheduled or transferred from one schedule to another.

APPENDIX II

Proceedings to add, delete, or change the schedule of a drug or other substance may be initiated by the Drug Enforcement Administration (DEA), the Department of Health and Human Services (the department), or by petition from any interested party.⁵ When a petition is received by the DEA, the agency begins its own investigation of the drug. Once the DEA has collected the necessary data, the DEA requests from the department a scientific and medical evaluation and recommendation as to whether the drug or other substance should be controlled or removed from control.

The vital issue is whether the drug or other substance has potential for abuse. Only drugs with a high potential for abuse will be controlled. There are five controlled substance schedules:

Schedule I

- The drug or other substance has a high potential for abuse.
- The drug or other substance has no currently accepted medical use in treatment in the United States.
- There is a lack of accepted safety for use of the drug or other substance under medical supervision.
- Some Schedule I substances are heroin, LSD, marijuana, and methaqualone.

Schedule II

- The drug or other substance has a high potential for abuse.
- The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
- Abuse of the drug or other substance may lead to severe psychological or physical dependence.
- Some Schedule II substances are morphine, hydrocodone, oxycodone and cocaine.

Schedule III

- The drug or other substance has a potential for abuse less than the drugs or other substances in Schedules I and II.
- The drug or other substance has a currently accepted medical use in treatment in the United States.
- Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.
- Some Schedule III substances are anabolic steroids, codeine and hydrocodone with aspirin or Tylenol, and some barbiturates.

⁵ Interested parties may include the manufacturer of a drug, a medical society or association, a pharmacy association, a public interest group concerned with drug abuse, a state or local government agency, or an individual citizen.

APPENDIX II

Schedule IV

- The drug or other substance has a low potential for abuse relative to the drugs or other substances in Schedule III.
- The drug or other substance has a currently accepted medical use in treatment in the United States.
- Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III.
- Some Schedule IV substances are Darvon, Talwin, Equanil, Valium and Xanax.

Schedule V

- The drug or other substance has a low potential for abuse relative to the drugs or other substances in Schedule IV.
- The drug or other substance has a currently accepted medical use in treatment in the United States.
- Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule IV.
- Some Schedule V substances are over-the-counter cough medicines with codeine.

OxyContin®

OxyContin® is a Schedule II substance that has continued to be abused in spite of its Schedule II status. OxyContin®, an oxycodone sustained-release formulation, is designed for use by patients with prolonged duration of moderate to severe pain. OxyContin® and morphine provide similar pain management results for most users. The controlled release method of delivery used in OxyContin® allows for a longer duration of drug action, and consequently, the manufacture of tablets containing larger doses of the active ingredient. Its availability in sustained-release formulations has increased the dosage forms from 10 milligrams up to 80 milligrams per tablet, making the sustained release formulation more attractive to narcotic abusers than traditional oxycodone formulations of 5 milligrams per tablet.